

Let us commit ourselves to the completion of the 1996 budget at the earliest possible date. Then let us recommit ourselves not to repeat anything like this in 1997 or ever again.

Mr. President, enough is enough.

#### PROVIDING FOR AN ADJOURNMENT OR RECESS OF THE TWO HOUSES

Mr. DOMENICI addressed the Chair.

The PRESIDING OFFICER. The Senator in New Mexico.

Mr. DOMENICI. I have been asked by the leader to make this unanimous-consent request. It has been cleared on the other side.

I ask unanimous consent that the Senate proceed to the immediate consideration of House Concurrent Resolution 157 just received from the House.

The PRESIDING OFFICER. The clerk will report.

The bill clerk read as follows:

A concurrent resolution (H. Con. Res. 157) providing for an adjournment or recess of the two Houses.

Mr. DOMENICI. I ask unanimous consent that the resolution be considered and agreed to and the motion to reconsider be laid upon the table.

The PRESIDING OFFICER. Without objection, it is so ordered.

The concurrent resolution (H. Con. Res. 157) was agreed to.

Mr. DOMENICI. Mr. President, I will speak for just a few moments. I understand there is still another Senator who wishes to speak, but I will not take very long.

#### MEDICARE FINANCING CRISIS

Mr. DOMENICI. Mr. President, I wish to speak for a moment about the Medicare Program which our senior citizens are very concerned about and most Americans are very concerned about.

Last year, the Medicare trustees told the President and the Congress that the Medicare Program is in financial crisis. Specifically, they said, and I quote, "The Federal hospital insurance trust fund which pays inpatient hospital expenses will be able to pay benefits for only about 7 years and is severely out of financial balance in the long run."

The Medicare trustees were even more blunt. "The Medicare Program is clearly unsustainable in its present form," they said. "The hospital insurance trust fund continues to be severely out of financial balance and is projected to be exhausted in 7 years."

That is what they said last year—7 years. In 1995, the trustees were telling us we have 7 years before the part A trust fund ran out of money. Last year's report projected that this fund would be insolvent in the year 2002. Based on the same data, I made a more precise prediction that bankruptcy would occur in early February 2002.

Very soon, we are going to receive from the Medicare trustees an annual

update to this report. I have looked at the data that the trustees used to generate their report, and I can say now that last year's projections were too optimistic. This year's report will show that the hospital trust fund is going bankrupt in the year 2001—not 2002. The projections were too optimistic last year.

A year ago my colleagues and I were urging the Senate and the President to follow the trustees' recommendation and address the Medicare financing crisis. This is why the reforms in Medicare were proposed last year. This Congress had a choice in 1995, and the choice was to address the Medicare financing crisis, restructure Medicare for the next century by providing seniors with more choices and containing costs to providers, or to ignore the crisis and let the problem languish for another year.

This Congress chose to act to try to save Medicare from the pending bankruptcy. When we made the choice, we had a 7-year window available to us and to the American people—7 years before part A would be bankrupt, without sufficient money to pay its bills.

Mr. President and fellow Senators, that is now down to 5 years. We spent a year trying to reform Medicare, only to have the reform fail and to have the President veto the reform measures. And we will soon officially hear from the trustees that we lost another year.

Last year we were told that we had until 2002. Now we will learn that we have until 2001. The Medicare part A problem is now worse than it was a year ago. Based on the data the trustees will be using in their annual report, which we have now had an opportunity to review, I can predict for the Senate and for those who are interested, the seniors across America, that the Medicare part A trust fund will be without sufficient funds to pay its bills in late May of 2001. Essentially, it will be bankrupt in May of 2001 instead of 2002. This is 5 years and 2 months from now—5 years and 2 months, not 7 years.

It is important to remember that while attention has focused on the impending bankruptcy of part A, the hospital plan, the underlying problem is the uncontrolled spending and the growth of the entire program.

Last year, the Congressional Budget Office projections showed that Medicare part A spending was growing at 8 percent a year, and it showed that part B spending was growing at 14 percent a year. There is no question that if we can slow the growth by reform, if we can make both part A and part B more streamlined and in touch and in tune with the modern delivery of health care, we can slow the growth. Our present spending is just not sustainable. Simply put, the trust fund will be bankrupt in 5 years and 2 months. The remainder is growing at 14 percent a year.

When we pursue that goal of making it sustainable, of slowing Medicare spending, one result will be that we

will save the part A trust fund, the hospital trust fund. The Balanced Budget Act passed this year by Congress—that is last year, in this year's cycle—and vetoed by the President, would have extended the life of part A past the year 2010. That same Medicare reform took the necessary steps toward addressing our long-term entitlement problem. Unfortunately, it, too, was vetoed when the Balanced Budget Act was vetoed.

I do not relish being the bearer of bad news. No one likes to hear that a program as valuable and as important as Medicare is in financial trouble. But we cannot simply bury our heads and hope that the problem will go away. It will not. We spent a year trying to address a problem here in the Congress, and now it appears that that effort may fall victim to a Presidential election. If we wait another year to address Medicare, we will be 4 years, if not shorter, from bankruptcy. I am concerned that 1 year from now I will be standing here on the floor of the Senate, reporting on the impending bankruptcy of the part A trust fund, and we will have spent a year doing nothing to address it.

I hope that is not the case. But I hope that more Senators and more leadership in this country will understand that if we do not change some things about the program there will be no program—not for the younger generation, but for seniors who are on the program right now. Because there are many senior citizens who are on the program right now who will still need hospitalization in the year 2001, 5 years from now. Unless we choose to do something now, it will not be available to them. We will have spent the money in the trust fund and the bills will be coming in faster than the revenue, and that equals bankruptcy.

So, I thought, today, after a careful study of the facts, that I would share this news, bring it to the floor and share it right now. I thought, as soon as I had it, I ought to share it with everyone. I believe what I am saying is correct. I believe I am slightly ahead of the trustees, but I know the information they have, and their experts, for that is shared information. There is no question in my mind the fund is going bankrupt faster than was estimated last year, and we are now 5 years and 2 months away from the fund not having money to pay the bills of senior citizens who are in hospitals.

I yield the floor.

Mr. KENNEDY addressed the Chair.

The PRESIDING OFFICER (Mr. BURNS). The Senator from Massachusetts.

Mr. KENNEDY. Are we in morning business at this time?

The PRESIDING OFFICER. We are.

Mr. KENNEDY. I ask unanimous consent I might be able to proceed in morning business.

The PRESIDING OFFICER. Without objection, it is so ordered.

## THE FDA REFORM MARKUP

Mr. KENNEDY. Mr. President, today when Americans get up in the morning and brush their teeth, they do not think about whether the toothpaste they are using is safe. When they eat their breakfast they do not think about the safety of the food they are eating. When they take a pill to treat an illness they do not worry about whether the drugs are safe. They do not worry about whether those drugs work. Americans have confidence in all of these products because the Food and Drug Administration is an independent agency with enormous credibility.

Yesterday, the Senate labor and human resource committee approved a FDA reform bill, S. 1477, that will destroy that confidence. S. 1477 will cripple the FDA, and turn many of its functions over to private industry.

The history of food and drug legislation is that we have learned from the tragedies of the past. The United States was fortunate to avoid the Thalidomide tragedy in the 1950's. But in the 1950's and 1960's, we did not avoid the tragedy of DES, Diethylstilbestrol, which causes cancer in the daughters of women who took it.

In the 1970's we did not avoid the tragedy of the Dalkon Shield, which caused thousands of cases of infertility in women who used it. In recent years we did not avoid the tragedy of the Shiley Heart Valve which broke and caused many deaths.

As a result of the Thalidomide tragedy, we strengthened our drug laws in 1962. As a result of the Dalkon Shield tragedy we strengthened our medical device laws in 1976 and we strengthened them again in 1990 after the Shiley valve tragedy.

Most recently, we reduced the delays in approving prescription drugs with user fees. As a result, we are now approving drugs faster than the United Kingdom. We have fixed the drug lag. In fact, the United States approves more important new drugs faster than any other country in the world.

But equally important, we have the best record in the world of blocking the approval of unsafe or ineffective drugs that have to be withdrawn after patients have been killed or injured.

The bill reported from the committee goes in the wrong direction. The lessons of the past have been turned on their heads, and those who have failed to learn from the history of Thalidomide, Dalkon Shield and DES, will condemn the American public to new device and drug tragedies. The basic theme of the legislation the committee approved is privatization. It says, "let us return to the days when drug manufacturers decided what was safe and effective." It says, "let device manufacturers pay private bodies to determine if their heart valves and pacemakers will help or harm patients, instead of relying on the scientists at the FDA, who have no interest except the public interest." If this bill is enacted into law, the Food and Drug Administration

will no longer have the principle responsibility for making critical decisions about the safety of the food supply and the safety and effectiveness of drugs and medical devices. Instead, those decisions will be made by private companies.

In the cases of medical devices, those companies will be selected and paid by the medical device industry to decide the safety and effectiveness of the products. No company that is paid to do product reviews can be objective, if future business depends on whether it grants a favorable decision. And to make the conflict of interest even more blatant, it will be up to the regulated industry to determine how much compensation the regulator will receive for the review.

Do you get this? That the medical device company will make the judgment as to which individual will come and inspect their particular medical device, and they, the inspector and the company, will work out the terms of payments.

If you were one of those inspectors, how long do you think you will make adverse judgments against those companies if you ever expect to get paid or hired again? You have a basic, fundamental conflict of interest. Compare this with the current situation where an inspector has no financial interest in making the judgment and bases decisions only upon pure science. That is how we do it at the present time.

As I said, we do it very successfully with regard to drugs and biologicals. It is slower with regard to medical devices, and various animal vaccines. We grant the FDA has not done well enough. But over the 30 years that our committee has been reviewing how to speed up the FDA, we have only been successful with one major change and that is when we put on the user fees, with the support of the pharmaceutical industry, with the support of President Bush, and with the support of Congress. And we have seen a dramatic change in terms of performance, in the approvals; significant reductions in terms of the considerations of those items. It has been successful. Now we are about to tamper with that particular effort, which has been reviewed by GAO, and by the Tufts Medical School, which has been constantly critical of the FDA, but all of them say that this is a program that is working.

It is not working as well in the device areas, as I mentioned, but what we are doing, I believe, is putting seriously at risk the successful programs that have been enacted in recent times.

In Britain in the last few weeks, we have had a stark demonstration of what can happen when the regulatory body charged with protecting the public interest has a conflict of interest.

Britain is in a food safety crisis over the meat from cattle with mad-cow disease because the Government paid too much attention to commercial interests and not enough attention to the health of consumers. Now, because

there is growing concern that mad-cow disease can be linked to a fatal disease in humans, British meat is being banned in every country in the world.

In Britain, the public is demanding to know why there is no independent body like America's Food and Drug Administration to protect the public. That is the question on the minds of British consumers.

How ironic that just a few days after the mad-cow disease disaster came to light, legislation was approved by our committee to dismantle the regulatory agency that is universally recognized abroad as the gold standard for the world. The FDA is our strongest defense against this kind of crisis in the United States. We have the safest food supply and the safest medical products in the world. We should not take any steps that jeopardize the confidence of American consumers in the safety of food and medical products. Yet this bill would seriously weaken current protections.

In addition to privatizing review of medical devices, this bill tells the public to trust drug manufacturers to make changes in the manufacturing process without FDA review to determine whether the changes affect safety or effectiveness. Companies under pressure to increase profits sometimes put profits first or simply sometimes make mistakes. In fact, most experts believe that mad-cow disease spread throughout Britain by a change in the manufacturing process of animal feed by some companies, the kind of change that S. 1477 leaves up to American companies to decide on their own.

Under this legislation, no change in the manufacturing process would require prior approval from the FDA. Yet, a change in the manufacturing process can determine whether a polio vaccine prevents polio or causes it. A change in the manufacturing process can determine whether a blood transfusion is life saving or whether it transmits AIDS or hepatitis to the patient. An independent FDA is needed to protect the public against these tragedies. Commercial interests should not prevail.

Further, the bill sets excessive time limits for review with no additional resources. The FDA will be unable to meet these requirements and do its job.

Even worse, the bill sets the wrong priorities so that every "me-too" drug of little additional therapeutic value receives the same priority as urgently needed new cures, and if FDA cannot meet the unrealistic time limits in the bill, the agency is required to contract its responsibility out, leading to further unacceptable privatization.

What did we do in the earlier legislation? We said on the priority drugs, we are going to make sure that these are going to be addressed within the first 6 months and then those that are of lesser significance and importance within 12 months. Therefore, the FDA is able to use some discretion in the areas of breakthrough drugs. The last drug on

AIDS was only about 2½ months under review because FDA had worked with the company further up the line to accelerate the consideration and the whole development time.

So FDA has been moving in the area of priority drugs. Now what does the legislation say? The legislation says you have to examine all of them, all of the drugs within the 6 months. The fact of the matter is, as anybody who understands what goes on out at the FDA knows, the vast majority of those other drugs are "me-too" drugs, not the breakthrough drugs.

So now instead of bringing focus and attention of the gifted and able scientists out at FDA on those drugs that could be breakthrough drugs in cancer, in AIDS, in hepatitis, in all kinds of diseases, we are going to divert their attention to looking after the "me-too" drugs that can make extra bucks for the pharmaceutical companies. Is the public interest served there? It is not.

This is a direct result of the pharmaceutical companies wanting to get some additional attention so that they can put on the market and promote and advertise and make additional profits from those "me-too" drugs. This is unwise, ill-conceived, and bad health policy. Mr. President, we all know that when the Congress previously acted in a bipartisan way with the Executive together with the pharmaceutical companies, all of them working together, setting the goals, setting the standards, setting the accountability on what the FDA should do—96 percent of the goals that were established were achieved, and now we are saying, "Well, that isn't good enough. That isn't good enough even though the GAO says we are the best in the world. That isn't good enough, and we are going to change that system," alter that system in a way which I think diminishes the efficiency of the FDA and could very well diminish the opportunities of moving the breakthrough drugs to the consumer in a more orderly, effective, and rapid way.

Mr. President, I was talking about the changes in both time limits for the consideration of priority drugs and also about the changes in the manufacturing processes that do not have to have prior approval by the FDA.

FDA is the most respected regulatory agency in the world. With too few resources now, FDA still gives us the safest food supply in the world and the best medical products. The FDA seal of approval is accepted with confidence and trusted worldwide. American companies benefit immensely from that confidence. This bill will turn that seal of approval into a label that cannot pass the truth-in-advertising test. Whether the product is heart valves or blood derivatives or vaccines or food, the American people will be at risk.

There are ways that FDA should improve. Some products do need to get to market faster. FDA should collaborate as much as possible with companies

and researchers to reduce the time of bringing safe and effective products to market. They are doing a good job now; they ought to do a better one. But we should not gut FDA's independence or the laws that give it that independence.

This legislation puts the commercial interests of companies ahead of the best interest of consumers. I am hopeful, Mr. President, that the provisions of S. 1477 that undermine health and safety can be revised before the bill comes to the floor. I know that Senator KASSEBAUM is committed to working with all interested Senators, and I pay tribute to Senator KASSEBAUM. She has spent an enormous amount of time herself on this issue. She has listened to different positions taken by those who are committed to the public health interests. She has listened to Members of the Senate.

I have the highest regard for her and the way that she has conducted the hearings and the leadership she has provided in this area, but I do find that I come out on a different side than she does with regard to the bill itself.

The present bill would destroy the safeguards protecting the American people that have been built up over the decades. It will cripple the world's best regulatory agency. It would be tragic if it became law. When the American people understand what is in it, I believe they will reject it.

Mr. President, I yield the floor.

Mr. INHOFE addressed the Chair.

The PRESIDING OFFICER. The Senator from Oklahoma.

#### READ AND SUCCEED—MEETING THE CHALLENGE OF ILLITERACY IN AMERICA

Mr. INHOFE. Mr. President, I rise today to share some thoughts on a subject of growing concern to many Americans, particularly to parents who seek a better and brighter future for their children through education.

It is that we are failing to teach our children to read effectively. In 1940, the literacy rate in the United States was 97 percent. It has now plunged to 76 percent—a rate which is lower than that of over 100 other nations.

To me, this is intolerable. America's future depends on restoring the reading skills of its people.

If we value our responsibility for leadership; if we seek to stay competitive in the world economy, we must address the problem of illiteracy in America.

We cannot stand by and watch our children sentenced to a life of mediocrity and illiteracy.

This problem exists in spite of the good intentions of Government and the expenditure of billions of taxpayer dollars over many years.

Reading is the most basic skill every child needs to achieve individual success and happiness—both in work and in life. Yet in failing to impart this skill effectively, we are directly under-

mining the success our children seek and deserve.

The evidence of our failure is all around us. Teachers and administrators see it in our schools, where 60 percent of entering college freshmen find themselves in need of remedial courses in reading or math.

Employers and businesspeople see it in the workplace, where industry spends exorbitant amounts on employee remedial training in basic verbal skills. Researchers and scholars detect it in their studies.

Hardly a week goes by that we do not see stories in the media about declining test scores or startling accounts of the growing problem of lagging reading skills in America. For example:

According to the U.S. Department of Education report known as the National Assessment of Education Progress [NEAP], "the average reading proficiency of 12th grade students declined significantly from 1992 to 1994."

This important study is widely considered to be one of the best barometers of overall student achievement. It reported that "70 percent of 4th graders, 30 percent of 8th graders, and 64 percent of 12th graders did not attain a proficient level of reading." In other words, these students did not reach a minimum skill level in reading which is considered necessary to do the work at that grade level.

According to a recent 5-year study, entitled "Adult Literacy in America," conducted by the National Center for Education Statistics, similar startling results were found. It stated that: 42 million Americans, 22 percent of the population cannot read; 50 million, 27 percent, can recognize so few printed words they are limited to a fourth or fifth grade reading level; 55 to 60 million, 30 percent, are limited to sixth, seventh, or eighth grade reading levels; only 30 million, 16 percent, have ninth and tenth grade reading levels; only 6 to 7 million, 3.5 percent, demonstrated skills necessary to do college level work.

SAT scores have declined steadily for most of the last 35 years. Verbal achievement has declined by nearly 90 points since 1960.

A U.S. Department of Labor study found that 20 percent of U.S. high school graduates could not even read their diplomas.

Mr. President, this is serious. All of this has consequences—in our economy, in our standard of living, in our competitive position in the world, and in our national security. For example:

The lower the literacy rate: the less productive our economy becomes, the less hours are worked and the less money they make in the form of wages and income, the higher the incidence of crime and welfare and their costs to society, the less effectively we are able to compete in world markets, the less capability we will have in our Armed Forces which are increasingly dependent on advanced technology and highly trained personnel as opposed to just sheer numbers.